Remarks

I. Status of the Claims

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 38, 40-72 and 110-145 are pending in the application, with claims 38, 73, 102, 103, and 113 being the independent claims. Claims 38, 40-72 and 110-145 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. New claims 146-203 are sought to be added. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

II. The Amendments

New claims 146-203 are directed to methods of treating, alleviating and reducing one or more symptoms of allergic disease or non-allergic inflammatory disease by administering an extract of kiwifruit of the genus Actinidia to a mammal in need thereof in an amount sufficient to treat, alleviate or reduce one or more symptoms of allergic disease or non-allergic inflammatory disease, wherein the allergic disease is selected from the group consisting of: anaphylaxis, allergic rhinitis, allergic conjunctivitis, urticaria, insect allergy, food allergy and drug allergy and wherein the non-allergic inflammatory disease is selected from the group consisting of: systemic lupus erythematosus, retinal inflammation, gastritis, retinopathy, hepatitis, enteritis,

pancreatitis and nephritis. The methods of the present invention are also directed to the in vivo effects of kiwifruit extract administration (*i.e.* modulating IgE, IgG1, IgG2, Th1 cytokine, and Th2 cytokine serum levels). The methods of the present invention also recite the treatment of specific symptoms associated with allergic and non-allergic inflammatory diseases, such as histamine production and edema.

Support for the new claims can be found inter alia in the disclosure as follows:

CLAIM	SUPPORT
147	See, for example, Example 2.
149, 178	See, for example, page 5, line 23-27; page 6, lines 5-7; and page 6 lines 27-29.
150, 180	See, for example, page 6, lines 31-32.
151, 181	See, for example, page 5, lines 18-21.
152, 153, 154, 182, 183, 184	See, for example, page 6, lines 34-37; and page 7, line 1.
155, 185	See, for example, page 13, line 5.
156, 186	See, for example, page 8, lines 34-36.
157, 187	See, for example, page 10, lines 1-9.
146, 148, 160	See, for example, Experimental Example 7.
159-167, 188-196	See, for example, page 7, lines 20-32; and Example 1.
168, 197	See, for example, page 9, lines 1-3.
169, 198	See, for example, page 9, lines 27-31.
170-174, 199-203	See, for example, page 9, lines 9-10; page 10, lines 26-29; page 12, lines 3-4; and page 12, lines 19-25.
175, 179	See, for example, page 5, lines 23-27; and page 6, lines 31-32.
176	See, for example, Example 5.
177	See, for example, Example 6.

Accordingly, no new matter is believed to have been added by the amendments, and their entry is respectfully requested.

III. The Rejections

A. Rejections Under 35 U.S.C. § 112

Claims 38, 40-72, and 110-145 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner has specifically objected to the phrase "reduce the risk [of allergic disease or non-allergic inflammatory disease in a mammal]." The Examiner has stated that this claim limitation "was not described in the application as filed, and persons skilled in the art would not recognize in the Applicant's disclosure a description of the invention as presently claimed." *See* Office Action, page 2. Applicants respectfully traverse this rejection.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor has possession of the claimed invention. *See Regents of the Univ. of Cal. v. Eli Lilly & Co.,* 119 F.3d 1559, 1566 (Fed. Cir. 1997); *see also* M.P.E.P. § 2163. An Applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formulas that fully set forth the invention. *See* M.P.E.P. § 2163, citing *Lockwood v. American Airlines, Inc.,* 107 F.3d 1565, 1572 (Fed. Cir. 1997). "The written description requirement does not require the applicant 'to describe exactly the subject matter claimed'." *Union Oil Co. v. Atlantic Richfield Co.,* 208 F.3d 989 (Fed. Cir. 2000); *see also* M.P.E.P. § 2163.02 ("The subject matter of the claim need not be described literally (i.e., using the same terms or in haec verba) in order for the disclosure to satisfy the description requirement.").

Applicants submit that the specification adequately describes the claimed invention such that a person of ordinary skill in the art would reasonably conclude that

the inventors were in possession of methods for reducing the risk of allergic disease or non-allergic inflammatory disease requiring the administration of extracts of kiwifruit of the genus Actinidia. For example, the specification in Example 6, describes the application of a kiwifruit extract (200 mg/kg in water) as reducing the risk of non-allergic inflammation caused by the subsequent application of arachidonic acid to mice ears. *See* page 28, lines 25-25 and page 29, lines 1-10. In fact, the application of the kiwifruit extract was able to reduce the risk of a symptom of non-allergic inflammation, edema, by up to 62.5%.

Furthermore, a specification need not disclose what is well known to those skilled in the art and preferably omits that which is well known to those skilled and already available to the public. *In re Buchner,* 929 F.2d 660, 661 (Fed. Cir. 1991); *Hybritech, Inc., v. Monoclonal Antibodies, Inc.,* 802 F.2d 1367, 1384 (Fed. Cir. 1986). Applicants submit that one of skill in the art would readily understand, at the time the present application was filed, that a number of symptoms are associated with allergic disease and non-allergic inflammatory disease, including edema, congestion, tenderness of affected areas that may also be more red in color and warm to the touch. Applicants also submit that one of skill in the art would also readily understand, at the time the present application was filed, that if a composition was administered and that that composition could reduce the edema, congestion, or tenderness of affected areas caused by the subsequent application of allergic compounds or inflammatory compounds, the agent essentially reduced the risk of symptoms of allergic disease or non-allergic inflammatory disease. As such, the specification does not need to explicitly recite "reduce the risk [of allergic disease or non-allergic inflammatory disease in a mammal."

Therefore, the general knowledge and level of skill in the art along with the specific guidance provided in the specification clearly provide the needed guidance to demonstrate Applicants were in possession of methods for reducing the risk of allergic disease and non-allergic inflammatory disease requiring the administration of extracts of kiwifruit of the genus Actinidia.

Nevertheless, solely in an effort to expedite prosecution, and without acquiescing to the propriety of the rejection, Applicants have canceled claims 38, 40-72, and 110-145. Thus, the rejection is moot.

B. Rejections Under 35 U.S.C. § 103

Claims 38, 40-59, 62, 65-67, and 110-112 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Murad (U.S. Pat. No. 6,630,163) in view of Endres *et al.* (German Pat. Appl. No. DE 19758090 A1, Abstract). Applicants respectfully traverse the rejection.

In order to establish a *prima facie* case of obviousness, three requirements must be met. First, all the claim limitations must be taught or suggested by the prior art. *See In re Royka,* 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *See In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). Third, there must be a reasonable expectation of success. *See In re Merck & Co., Inc.,* 800 F.2d 1091, 213 USPQ 375 (Fed. Cir. 1986). The teaching or suggestion to make the claimed combination and the reasonable expectation of

success must both be found in the prior art, not in Applicants' disclosure. *See In re Vaeck,* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Additionally, when "formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed." Memorandum from the United States Patent and Trademark Office, "Supreme Court decision on *KSR Int'l Co. v. Teleflex Inc.,*" (May 3, 2007) at page 2. However, the Examiner has failed to provide such a sufficient reason.

As applied to new claims 146-203, Applicants respectfully assert that Murad merely mentions the use of fruit extracts generally to treat a multitude of inflammatory skin diseases, and mentions kiwi in a laundry list of fruits. Murad does not disclose treatment of ***allergic disease or non-dermatological inflammatory diseases***. Murad contains only one working example in which fruit is used for any therapeutic or preventive purpose: treating sun-exposed skin. Murad provides a laundry list of inflammatory dermatoses that are contemplated for treatment, however, there is no working example showing that the Murad compositions were ever used to treat such conditions, and Murad provides no specific teaching that would guide one of ordinary skill in the art on how the compositions would be used for such purposes. Moreover, Murad does not discuss IgE, IgG1, IgG2a, Th1 cytokine, Th2 cytokine serum levels, nor does it discuss histamine release or edema. As such, the reference does not teach all of the claim limitations of the new claims presented hereto.

While Endres mentions using *Actinidia arguta* extracts to treat inflammatory dermatological conditions, Endres does not disclose treatment of ***allergic or non-***

dermatological inflammatory disease with extracts of kiwifruit of the genus Actinidia. Therefore, there is no suggestion or motivation to treat allergic or non-dermatological inflammatory disease in a mammal in need thereof with kiwifruit extracts of the claimed invention, simply by combining the Murad and Endres references. Additionally, the references combined fail to provide a reasonable expectation for successfully treating allergic or non-dermatological inflammatory disease by administering a kiwifruit extract to a mammal in need thereof. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the outstanding rejection.

The Examiner has also rejected claims 38, 40-59, 62, 65-67, and 110-112 under 35 U.S.C. § 103(a) as allegedly unpatentable over Murad (U.S. Pat. No. 6,630,163) in view Udagawa (Japanese Pat. Appl. No. JP 61140510 A, Abstract). Applicants respectfully traverse the rejection. In so far as the rejection may apply to the amended claims, Applicants provide the following comments.

Udagawa mentions the use of *Actinidia kolomikta* and *Actinidia polygama* fruit extracts in cosmetics but does not disclose the use of kiwifruit extracts or kiwifruit species' (*Actinidia arguta, Actinidia kolomikta* or *Actinidia polygama)* extracts in pharmaceutical compositions. This reference also does not discuss serum IgE, IgG1, IgG2, Th1 cytokine, Th2 cytokine levels, histamine production or edema. As such, Udagawa does not teach addressing the mechanism underlying allergic and non-dermatological inflammatory disease or administering kiwifruit extracts to pharmaceutically treat any condition to a mammal in need thereof, let alone the ***allergic and non-dermatological inflammatory conditions*** of the present invention.

For the reasons provided above, Applicants assert there is no suggestion or motivation to treat allergic or non-dermatological inflammatory disease with the claimed extracts of kiwifruit of the genus Actinidia simply by combining the Murad and Udagawa references. Additionally, the references combined fail to provide a reasonable expectation for successfully treating allergic or non-dermatological inflammatory disease by administering a kiwifruit extract to a mammal in need thereof. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the outstanding rejection.

The Examiner has also rejected claims 38, 40-64, 69-72, 110-135, and 142-145 under 35 U.S.C. § 103(a) as allegedly unpatentable over Forastiere *et al.* Thorax 55:283-288 (2000) in view of Endres and/or Udagawa. Applicants respectfully traverse the rejection. In so far as the rejection may apply to the amended claims, Applicants provide the following comments.

Forastiere discusses treating asthma symptoms by administering common kiwifruit. This reference does not disclose administering any type of kiwifruit extract. Nor does this reference teach alleviating the symptoms of anaphylaxis, allergic rhinitis, allergic conjunctivitis, allergic dermatitis, atopic dermatitis, contagious dermatitis, urticaria, insect allergy, food allergy or drug allergy by administering kiwifruit extracts. Thus, Forastiere fails to teach each and every limitation of the pending claims.

Applicants respectfully assert that there is no suggestion or motivation to combine the Forastiere and Udagawa references, either within the references or within the knowledge of ordinary skill in the art. Even if the references are combined, the references fail to provide a reasonable expectation for successfully treating the claimed

allergic or non-dermatological inflammatory conditions with an extract of kiwifruit of the genus Actinidia to a mammal in need thereof, as the references discuss diverging uses for their compositions. The therapeutic use of the Forastiere kiwifruit differs substantially from the cosmetic use of the Udagawa kiwifruit extracts.

Applicants also respectfully assert that there is no suggestion or motivation to combine the Forastiere and Endres references either within the references or within the knowledge of one of ordinary skill in the art. Even assuming, *arguendo*, that the cited art was combined, the claimed invention would not be obtained as neither Forastiere nor Endres teaches treating ***allergic or non-dermatological inflammatory conditions*** with a ***an extract of kiwifruit of the genus Actinidia*** to a mammal in need thereof, where the allergic disease is anaphylaxis, allergic rhinitis, allergic conjunctivitis, allergic dermatitis, atopic dermatitis, contagious dermatitis, urticaria, insect allergy, food allergy or drug allergy. Endres does not fill any of the deficits that exist in Forastiere: (1) providing a kiwifruit and not an extract, (2) treating non-dermatological inflammatory conditions, and (3) treating the above-outlined allergic conditions.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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